Improving selection of patients with less than 60% asymptomatic internal carotid artery stenosis for follow-up carotid artery duplex scanning

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Purpose: **The Asymptomatic Carotid Atherosclerosis Study (ACAS) indicated significant benefit from endarterectomy compared with medical therapy for patients with 60% to 99% asymptomatic internal carotid artery (ICA) stenoses. To date, optimal selection of patients for vascular laboratory follow-up to determine progression from <60% to ≥60% asymptomatic ICA stenosis is unknown. To determine which patients with <60% asymptomatic ICA stenoses are at greatest risk for short-term progression to ≥60% without symptoms, we reviewed vascular laboratory results and clinical risk factors of consecutive patients who were prospectively observed in a study of atherosclerosis progression.**

Methods: **Carotid duplex studies were obtained every 6 months and were reviewed for progression from <60% to ≥60% asymptomatic ICA stenosis by using criteria that were developed and reported by our laboratory. Clinical risk factors and velocities from initial duplex scans were analyzed for association with progression from <60% to ≥60% ICA stenoses without symptoms.**

Results: **Two hundred sixty-three patients (mean age, 66 years) with 434 asymptomatic <60% ICA stenoses were prospectively observed for a mean of 20 months, with a mean of four examinations per patient. Seventeen patients (6.5%) and 18 ICAs (4%) progressed without symptoms to ≥60% ICA stenoses at a mean of 18 months. Clinical risk factors associated with progression to ≥60% asymptomatic ICA stenosis included elevated systolic blood pressure and decreased ankle-brachial index ($p = 0.05$). The mean initial ICA peak systolic velocity (PSV) in ICAs that progressed to ≥60% asymptomatic stenoses was 180 cm/sec, compared with 104 cm/sec in asymptomatic ICAs that did not progress to ≥60% ($p = 0.0003$). Thirty-one percent of asymptomatic ICAs that had initial PSVs of 175 cm/sec or greater progressed to ≥60% stenosis, whereas only 1.8% that had initial PSVs less than 175cm/sec progressed to ≥60% asymptomatic stenoses ($p < 0.001$). The life-table–determined rate of freedom from progression to ≥60% stenosis was 94% at 4 years for asymptomatic ICA lesions that had initial PSVs less than 175 cm/sec, compared with 14% at 3 years for lesions that had initial PSVs ≥175 cm/sec.**

Conclusions: **Early progression from <60% asymptomatic ICA stenoses to ≥60% asymptomatic ICA stenoses occurs infrequently. Patients who are at the greatest risk of early progression without symptoms to an ACAS-positive lesion can be identified from the ICA PSV at their initial duplex examination. Early vascular laboratory follow-up of asymptomatic ICA stenoses may be limited to a relatively small group. (J Vasc Surg 1996;24:580-7.)**

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The Asymptomatic Carotid Atherosclerosis Study (ACAS) demonstrated benefit from prophylactic carotid endarterectomy for patients who have ≥60% asymptomatic internal carotid artery (ICA) stenoses.[1] Because these lesions are asymptomatic, their detection requires a carotid screening study, usually duplex scanning. Most screening studies do not reveal a ≥60% stenosis,[2-4] and these patients must then be considered for further follow-up. Although it is known that ICA stenoses generally worsen over time,[5-9] the spe-

cific question of which <60% stenoses are most likely to progress to ACAS-threshold lesions (≥60% stenoses) has not been addressed. This information would be useful in constructing guidelines for the vascular laboratory follow-up of patients who have known, but <60%, ICA stenoses.

We recently reported duplex criteria that predicted the presence of a ≥60% angiographic ICA stenosis with 90% overall accuracy and a positive predictive value of 92%.[10] In this study we report the results of the prospective follow-up of 263 patients who had known peripheral vascular disease and whose asymptomatic carotid artery stenoses were evaluated by serial duplex scanning. The goal was to determine patient-specific and duplex-specific variables that identified the patients who had <60% ICA stenoses that were most likely to progress without symptoms to ≥60% ICA stenoses.

PATIENTS AND METHODS

Since 1991 we have enrolled patients in a prospective longitudinal study of atherosclerotic disease progression.[11] Eligible patients include those 40 to 80 years of age who have symptomatic atherosclerotic vascular disease (defined as a history of claudication, rest pain, ischemic ulceration, previous infrainguinal bypass, transient ischemic attacks, stroke, or carotid endarterectomy). When entered into the study, patients undergo a cardiovascular-directed history and physical examination and vascular laboratory evaluation. Vascular laboratory studies include segmental leg blood pressure measurements, treadmill test, and carotid duplex scanning. Duplex scans are performed in a standard fashion[12] with an Acuson 128 duplex scanner (Acuson Inc., Mountain View, Calif.). All patients undergo a clinical laboratory evaluation, which includes tests for serum electrolytes, blood urea nitrogen, creatinine, blood glucose, fasting cholesterol, and triglyceride levels, as well as white blood cell, hemoglobin, hematocrit, and platelet counts. Coagulation studies that are routinely obtained include tests for prothrombin and partial thromboplastin times and anticardiolipin antibody, antithrombin III, protein C, protein S, and lipoprotein (a) levels. The taking of history, physical examination, and vascular laboratory tests are repeated every 6 months.

For this study all enrolled patients at study entry who had at least one asymptomatic <60% ICA stenoses that remained asymptomatic during follow-up were analyzed. Duplex examinations of asymptomatic <60% ICAs taken at the time the patient entered the study were reviewed to identify patients whose ICAs progressed to ≥60% asymptomatic stenosis during follow-up. Duplex distinction between <60% and ≥60% ICA stenoses was made on the basis of criteria that were previously published in a combined study from our institution and the University of Washington.[10] Specifically, the combination of a ICA peak systolic velocity (PSV) greater than 260 cm/sec and an end-diastolic velocity greater than 70 cm/sec (92% positive predictive value) was used to identify a ≥60% ICA stenosis. Serial duplex examinations were reviewed to detect patients in whom ≥60% asymptomatic ICA stenoses developed during follow-up.

Patients who had asymptomatic ICA stenoses that progressed without symptoms to ≥60% ICA stenoses during follow-up were compared with patients whose stenosis did not progress to a ≥60% asymptomatic stenosis. These comparisons included age, sex, lipid levels, the presence or absence of diabetes mellitus (receiving oral hypoglycemic agents or insulin), smoking (current or quit), systolic blood pressure, ankle-brachial index (ABI) at study entrance, the presence of known coronary artery disease (history of myocardial infarction, angina pectoris, coronary artery bypass grafting procedure, transluminal coronary angioplasty, or congestive heart failure), presence of renal insufficiency (dialysis-dependent or creatinine level >2.0 mg/dl), or a hypercoagulable disorder. In addition, the presence of contralateral carotid symptoms or contralateral carotid occlusion when entered into the study and their development during follow-up were also compared.

Initial carotid duplex studies were analyzed for duplex variables (ICA PSV, end-diastolic velocity, and ICA/common carotid artery [CCA] PSV ratio) associated with subsequent progression to ≥60% ICA stenosis without symptoms.

Data were stored in a Dataease file management database (Dataease Inc., Trumbull, Conn.). The significance of associations among variables was analyzed with two-way contingency tables and χ^2 tests for categoric variables. Comparison between two groups was analyzed by a two-sample Student t test for continuous variables. The probability of various factors influencing the progression of ICA stenosis was assessed by multivariate, stepwise logistic regression analysis with the statistical analysis system package (SAS Institute; Cary, N.C.). The log-rank method was used to compare life-table results.[13] Results were considered significant if $p < 0.05$.

RESULTS

Patients and ICA progression. Two-hundred sixty-three patients who had 434 asymptomatic ICAs

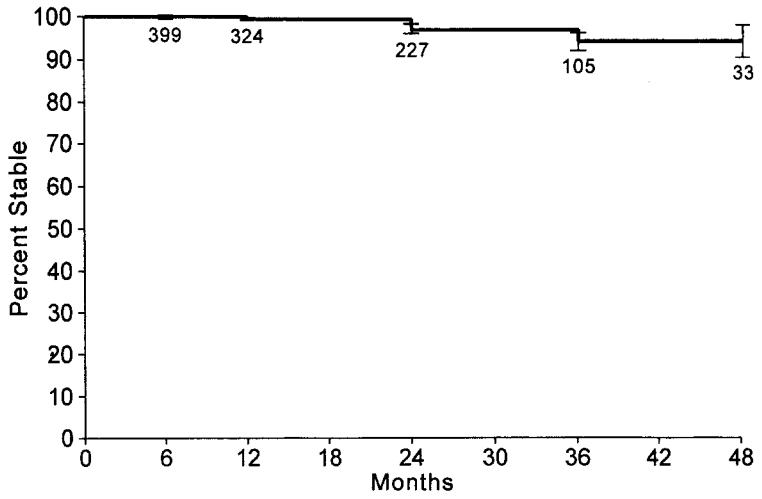

Fig. 1. Four-year life-table–determined rate of freedom from progression to ≥60% stenosis in 399 asymptomatic ICAs with <60% stenosis and initial PSVs less than 175 cm/sec.

Table I. Clinical risk factors for asymptomatic progression form <60% to ≥60% ICA stenosis

Risk factor	*Progressors (SD)*	*Nonprogressors (SD)*	*p**
Age (mean)	69	66	0.11
Men	65%	63%	0.86
Smoking	94%	82%	0.44
Diabetes	24%	22%	0.88
Cardiac disease	53%	48%	0.67
Contralateral symptoms	47%	31%	0.18
Creatinine level ≥2.0 mg/dl	0%	2.4%	0.52
Positive hypercoaguable state screening	5.9%	3.7%	0.64
ABI (mean)	0.74 ± 0.18	0.85 ± 0.22	0.05
Systolic blood pressure (mm Hg)	164 ± 21	153 ± 23	0.05
Triglyceride levels (mg/dl)	262 ± 172	230 ± 150	0.46
Cholesterol level (mg/dl)	211 ± 43	220 ± 44	0.42

*Logistic regression analysis.

were prospectively observed for a mean of 20 months (range, 6 to 42 months). Two hundred forty-six patients (94%) had 416 asymptomatic ICAs (96%) that remained <60% stenotic, as compared with 17 patients (6%) with 18 asymptomatic ICAs (4%) that progressed to ≥60% ICA stenosis during follow-up. Of the 17 patients who had an ICA that progressed to ≥60% stenosis during follow-up, eight underwent carotid endarterectomy after consultation with their referring physician. Preoperative angiography confirmed a ≥60% ICA stenosis in all patients who underwent surgery. No perioperative strokes or deaths occurred. Nine patients whose asymptomatic ICA progressed to ≥60% stenosis continue to be observed, and all remain without symptoms. Serial duplex studies for the nine patients who did not undergo surgery after progression to ≥60% asymptomatic ICA stenosis had PSVs of 260 cm/sec or greater in 23 of 28 follow-up studies. Three of the asymptomatic ICAs that progressed and did not undergo carotid endarterectomy vacillated above and below the cutoff PSV of 260 cm/sec during follow-up and likely represented borderline lesions.

Clinical risk factor analysis. A comparison of clinical risk factors between patients who had asymptomatic ICA progression to ≥60% stenoses and those who did not are shown in Table I. Patients whose ICA progressed to ≥60% asymptomatic stenosis during follow-up had a significantly greater systolic blood pressure ($p = 0.05$) and a lower initial resting ABI ($p = 0.05$) than those patients whose asymptomatic ICAs remained <60% stenotic.

Duplex analysis. A mean of four carotid duplex examinations per patient were performed during follow-up (range, two to seven). When entered into the study, there were two contralateral ICA occlusions (11%) in the patients who had a <60% ICA stenosis progress to ≥60% stenosis, compared with

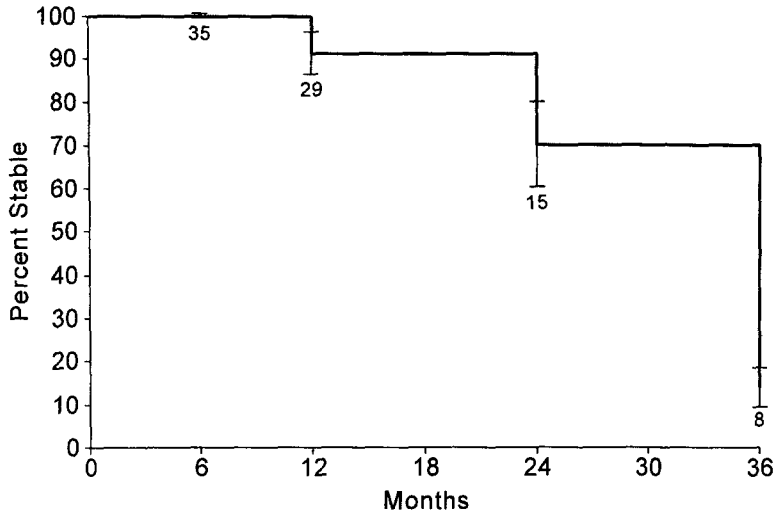

Fig. 2. Three-year life-table–determined rate of freedom from progression to ≥60% stenosis in 35 asymptomatic ICAs with <60% stenosis and initial PSVs 175 cm/sec or greater.

Table II. Rate of freedom from progression from <60% asymptomatic ICA stenosis to ≥60% asymptomatic ICA stenosis (initial ICA PSV <175 cm/sec)

Interval (mo)	*At risk*	*Progress*	*Withdrawn*	*Interval stable*	*Cumulative stable*	*SE*
0	399	0	0	1.000	1.000	0.0000
6	399	0	75	1.000	1.000	0.0054
12	324	1	96	0.996	0.996	0.0035
24	227	4	118	0.976	0.972	0.0108
36	105	2	70	0.944	0.944	0.0218
48	33	0	33	1.000	0.944	0.0389

10 contralateral ICA occlusions (2.4%) in the 416 ICAs that remained <60% ($p = 0.14$). No <60% asymptomatic ICA stenosis progressed to occlusion during follow-up.

The mean initial ICA PSV was 180 ± 63.3 cm/sec in the 18 asymptomatic <60% stenotic ICAs that progressed without symptoms to ≥60% stenoses, compared with a mean initial PSV of 104 ± 39 cm/sec in the 416 asymptomatic ICAs that remained <60% during follow-up ($p = 0.0003$). The mean initial ICA/CCA PSV ratio was 2.39 ± 1.12 in the 18 asymptomatic <60% stenotic ICAs that progressed to ≥60% stenosis, compared with a mean initial ICA/CCA PSV ratio of 1.41 ± 0.71 in the 416 asymptomatic ICAs that remained <60% during follow-up ($p < 0.001$). End-diastolic velocity alone did not correlate with progression from <60% to ≥60% ICA stenosis.

Thirty-one percent of asymptomatic ICAs that had initial PSVs of 175 cm/sec or greater progressed to ≥60% asymptomatic stenoses, compared with only 1.8% of asymptomatic ICAs that had initial PSVs less than 175 cm/sec ($p < 0.001$). The life-table–determined rate of freedom from progression to ≥60% ICA stenosis for the <60% asymptomatic ICAs that had initial PSVs less than 175 cm/sec was 100% at 1 year and 94% at 4 years (Table II, Fig. 1). The life-table–determined rate of freedom from progression to ≥60% ICA stenosis for those <60% asymptomatic ICAs that had initial PSVs of 175 cm/sec or greater was 91% at one year and 14% at 3 years (Table III, Fig. 2; $p < 0.0005$).

DISCUSSION

Several studies have used duplex scanning to examine the progression of asymptomatic ICA stenoses.[5-9] The studies are summarized in Table IV. These reports document that in the intermediate term a minority of carotid stenoses progress and that only a small number (<10%) of these stenoses will have symptoms. Most investigators have noted that greater degrees of carotid stenosis are associated with a higher risk of symptoms, occlusion, or both. No study to date, however, has specifically addressed the question

Table III. Rate of freedom from progression from <60% asymptomatic ICA stenosis to ≥60% asymptomatic ICA stenosis (initial ICA PSV ≥175 cm/sec)

Interval (mo)	*At risk*	*Progress*	*Withdrawn*	*Interval stable*	*Cumulative stable*	*SE*
0	35	0	0	1.000	1.000	0.0000
6	35	0	6	1.000	1.000	0.0054
12	29	2	12	0.913	0.913	0.0500
24	15	3	4	0.769	0.702	0.0989
36	8	6	1	0.200	0.140	0.0459

Table IV. Additional reports examining the natural history of asymptomatic ICA stenosis

Date	*Author*	*n*	*Mean follow-up*	*Percent progression*	*TIA*	*Stroke*	*Occlusion*
1984	Roederer	167	36 mo.*	60%†	6 (3.6%)	4 (2.4%)	10 (6%)
1990	Norris	696	41 mo.	Not given	75 (11%)	29 (4.2%)	Not given
1992	Ellis	1198	20 mo.	3.1%‡	33 (2.8%)	27 (2.3%)	Not given
1992	Shanik	188	48 mo.	28.6%	6 (3.2%)	10 (5.3%)	12 (6.4%)
1993	Bock	242	27 mo.	Not given	20 (8.3%)	15 (6.2%)	Not given
1995	Johnson	232	84 mo.§	23%‡	Not given	12 (5.2%)	10 (4.3%)

*Mean follow-up not given (patients studied for up to 36 months).
†Defined as a change in carotid stenosis of one or more spectral categories.
‡Defined as development of >50% stenosis.
§Mean follow-up not given (life table data available for 7 years).

of which patients who have asymptomatic ICA stenoses are most likely to progress without symptoms to the threshold level of ICA stenosis that was identified by ACAS as statistically benefiting from prophylactic carotid endarterectomy.

With the results of the ACAS study many physicians may wish both to detect asymptomatic ICAs between 60% and 99% stenosis and to establish a plan for vascular laboratory follow-up for patients who have known atherosclerotic disease but <60% asymptomatic ICA stenosis. Accordingly, we developed vascular laboratory criteria that specifically address the ACAS threshold level of ICA stenosis.[10] Our current study used these criteria in a prospectively observed cohort with <60% asymptomatic ICA stenosis to develop guidelines for vascular laboratory follow-up of these patients.

Although clinical risk factors for progression from <60% asymptomatic ICA stenosis to ≥60% ICA stenosis in this study included both an elevated systolic blood pressure and a low ABI, the data presented herein indicate that the schedule for vascular laboratory follow-up of asymptomatic ICA stenoses that occur in patients who have symptomatic atherosclerotic vascular disease can probably be best based on initial carotid artery duplex findings. Patients who have ICA peak systolic velocities less than 175 cm/sec have very little risk of the stenosis progressing to a ≥60% asymptomatic ICA stenosis in the intermediate term; in our experience only 5.6% of stenoses progressed to an ACAS-threshold lesion within 4 years after their screening carotid duplex examination. It therefore appears appropriate to delay subsequent carotid duplex examinations in such patients for 3 or 4 years, provided that they remain without symptoms. Even patients who have a stenosis and whose initial ICA peak systolic velocity is greater than 175 cm/sec are at low risk for progression without symptoms to a ≥60% ICA stenosis at 1 year, but by 3 years 86% of these patients will have their stenosis progress from <60% to a ≥60% asymptomatic ICA stenosis. It would appear prudent for these patients to undergo follow-up carotid artery duplex studies at least yearly provided that they remain a clinical candidate for prophylactic carotid endarterectomy.

The high rate of progression to ≥60% asymptomatic ICA stenosis for ICAs that have peak systolic velocities greater than 175 cm/sec may, in part, be explained by the patient cohort included in the study. To be included in the study, all of the patients (those whose stenoses progressed and those whose stenoses did not) had sufficiently advanced atherosclerotic arterial disease to have produced symptoms in the opposite carotid artery or in the legs. The patients may therefore be preselected for their arterial disease to progress once it reaches a certain level. The recommendations for carotid duplex follow-up examinations that were stated above may in fact be too liberal for patients who have no symptoms of arterial disease and a <60% asymptomatic ICA stenosis detected on duplex scanning. Clearly additional studies that examine the progression of asymptomatic ICA

stenosis in different vascular disease cohorts will be useful in optimizing recommendations for follow-up carotid ultrasound studies. For the present, in patients who have symptomatic arterial disease, we recommend that more frequent follow-up of patients who have asymptomatic <60% ICA stenosis be performed if the patients have initial ICA peak systolic velocities greater than 175 cm/sec.

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DISCUSSION

Dr. R. Eugene Zierler (Seattle, Wash.). Randomized clinical trials such as the North American Symptomatic Carotid Endarterectomy Trial and ACAS have provided us with specific clinical guidelines regarding the indications for performing carotid endarterectomy in patients who have symptomatic or asymptomatic carotid artery disease. In these trials, a particular degree of carotid stenosis severity emerged as the threshold for recommending surgical treatment. The results of these trials, however, are not much help in establishing the optimal protocols for managing patients who have degrees of carotid stenosis that are below the surgical threshold. Furthermore, those clinical trials only documented the severity of carotid artery disease at the point of randomization, not at the time a subsequent neurologic event occurred. Thus the actual degree of stenosis that is associated with neurologic events remains unknown unless arteriographic or duplex scans are repeated.

Changes in the severity of carotid artery disease over time are clearly of critical importance in determining the most appropriate follow-up protocol for patients who have mild to moderate degrees of asymptomatic carotid stenosis. Natural history studies provide the basic information that is necessary for establishing these protocols. Ideally, natural history studies of atherosclerosis should indicate both the frequency and the rate of disease progression, as well as any factors associated with an increased risk of disease progression or clinical events.

This report addresses the issue of patients who have asymptomatic carotid artery disease and have lesions that do not meet the threshold for surgical treatment according to ACAS. A cohort of patients that met these general criteria was identified, and the patients were observed at 6-month intervals by previously validated duplex criteria. The PSV at the site of the lesion was found to be the most predictive parameter for progression from <60% to ≥60% ICA stenosis. The threshold value of 175 cm/sec appeared to reliably identify patients who had mild to moderate carotid disease and who were most likely to progress over time and meet the ACAS criteria for undergoing carotid endarterectomy.

These results are consistent with a similar natural history study from our own group that was published in the *Journal of Vascular Surgery* last year.[6] That study used serial duplex scans to evaluate carotid artery disease progression in 232 asymptomatic patients who had <80% stenoses and were observed for as many as 10 years. The cumulative risk of

progression to ≥80% stenosis was related to the initial severity of carotid disease, with 27% of the 50%-to-79% lesions but only 4% of the <50% lesions showing progression to ≥80% stenosis over 7 years. Thus the annual rate of progression to ≥80% stenosis was 3.7% for 50%-to-79% stenoses and 0.6% for <50% carotid lesions. These findings led to the recommendation for at least annual follow-up for patients who have asymptomatic 50%-to-79% carotid stenoses and follow-up at 2-year intervals for patients who have <50% lesions.

The authors of the study just presented recommend at least annual follow-up for patients who have asymptomatic carotid stenosis associated with a PSV of 175 cm/sec or greater and follow-up after an interval of 3 to 4 years for patients who have a PSV less than 175 cm/sec. Although this study raises a number of interesting questions, I will limit my list to the following three. First, the mean follow-up interval for the entire group of 263 patients was 20 months. What was the mean follow-up interval for the 246 patients who had asymptomatic internal carotid artery stenoses that remained at <60% compared with the mean follow-up interval for the 17 patients who had stenoses that progressed to ≥60%? If these groups were observed for widely disparate intervals, this factor could account for some of the differences observed. Second, the manuscript refers to nine patients who did not undergo surgery after progression to ≥60% asymptomatic internal carotid stenosis was observed. Serial duplex follow-up of these patients demonstrated PSVs of 260 cm/sec or greater in 23 of 28 studies. Does this mean that evidence of disease regression was present in some of these cases? Third, the clinical factors of elevated systolic blood pressure and lower initial ABI correlated with asymptomatic progression to a ≥60% ICA stenosis. Did these factors correlate with disease progression independent of the PSV? If so, should patients who have these risk factors be considered for more frequent duplex follow-up even if the PSV is less than 175 cm/sec?

This report is a valuable contribution to our understanding of the natural history of carotid artery disease, and the data presented will result in a more rational approach to the management of patients with less severe degrees of carotid stenosis.

Dr. Mark R. Nehler. This work compares two sample groups that contain markedly different numbers of patients. Clearly, care must be taken to avoid a type II error in data analysis. The mean follow-up was similar in both groups: 18 months in the patients who had asymptomatic ICA progression to ≥60% stenosis compared with 20 months for the patients whose asymptomatic ICAs remained <60%.

The nine patients who were observed who did not undergo surgery after ICA progression without symptoms to ≥60% stenosis had a total of 28 serial duplex examinations after progression. Two arteries had five duplex examinations that demonstrated PSVs lower than 260 cm/sec. These arteries represented either regression or were borderline lesions.

The influence of initial elevated systolic blood pressure and resting ABI were analyzed independent of the duplex velocities. Our goal was to develop an algorithm that was simple to use. The mean values for the initial systolic blood pressure and the lowest resting ABI in the two groups were not markedly different, despite the p value of 0.05.

Dr. Jerry Goldstone (San Francisco, Calif.). Dr. Whittemore, what do you do at your vascular center in the greater Boston area?

Dr. Anthony D. Whittemore (Boston, Mass.). With respect to carotid artery screening, cardiac surgeons seem to be divided even as to whether participation in the ongoing attempt to launch a multicenter trial to answer that question is justified. Many reasons for that divided opinion have been brought out this morning, but perhaps the main point is that screening at least identifies a patient population at risk, and what that risk is during cardiac and noncardiac surgery is still controversial.

Our philosophy is to screen patients who have severe claudication and other operative candidates, and those patients who undergo coronary bypass, with the understanding that we may not be repairing lesions in the 60% to 80% range, but we are at least identifying those patients at risk who require serial surveillance.

Dr. D. Eugene Strandness, Jr. (Seattle, Wash.). I think there is an important point here. From our studies and others, we now know what to tell a patient. I think this is very important. We know that the progression rate is very low in certain groups and is higher in others. This is very valuable information. The only question I would have is to ask Dr. Porter whether he thinks old geezer vascular surgeons ought to be screened.

Dr. John M. Porter. I think that we should be extremely kind to geezers. There are more geezers being created every day.

Dr. Strandness. The reason I bring this up, John, is because I do get scanned every year by Ms. Jean Primozich, and I watch her eyes more than anything else.

Dr. Porter. I don't know. I think this issue of screening is important. We like to screen all of our preoperative vascular patients who are having elective surgery. The issue of who's going to pay for the screening is a big-time problem, but we find a modest number of D-plus lesions in elective leg bypass, elective aneurysm patients, and insofar as the second surgery is elective, we recommend that the carotid artery be addressed first.

Dr. Strandness. I think that it is nice to be able to tell the patient that they have disease in this particular category. We know what the rate of progression is. They don't have to be screened except once every year or two. I think this is important, and I can't think of any information that's more comforting to a patient than saying, "Look, you don't have to worry about having a stroke from your carotid artery in the next 4 to 5 years."

Dr. Nehler. The medical community has spent a great deal of resources on multicenter trials to define the efficacy of carotid endarterectomy in asymptomatic patients who have appropriate lesions. Our job is to determine how to effectively locate patients who could potentially benefit from within our vascular population.

Dr. York N. Hsiang (Vancouver, British Columbia). That was a very nice study. I note that you were sponsored by the National Institutes of Health to look at a progression study. I was wondering if you were going to be sponsored by the same to look at a regression study.

I think some of the things that you talked about focus on disease and not the whole patient. What were the patient characteristics of those patients who progressed and those patients who did not progress?

In other words, what happened to the patients' smoking status, their obesity status, and their cholesterol levels? Were they taking any antioxidants or any other medications that could regress atherosclerosis, in particular the calcium channel blockers?

Dr. Nehler. Only initial lipid levels were measured in our protocol. We have no data regarding the other factors.